

United States Department of Agriculture

January 8, 2002

Marketing and Regulatory Programs

## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-03

Animal and Plant Health Inspection Service Subject: Issuance of Licenses

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants

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Veterinary Services Management Team Directors, Center for Veterinary Biologics

Area Veterinarians in Charge, VS

Center for

Veterinary Biologics Suite 104 510 South 17th Street Ames, IA 50010 (515) 232-5785 FAX (515) 232-7120

The purpose of this notice is to bring to the attention of interested parties licenses issued and terminated during the months of October, November, and December 2001. These do not include those licenses reissued to update pertinent information. A product license has been issued for each of the following:

True Name	Product Code	Establishment/ Permittee	Date
Bovine Rhinotracheitis-Parainfluenza <sub>3</sub> -	1071.22	Pfizer Inc.,	12/20/01
Respiratory Syncytial Virus Vaccine,		Est. 189	
Modified Live Virus			
Chicken Anemia Virus Vaccine, Live Virus	10A1.01	Biomune Co.,	11/01/01
		Est. 368	
Bovine Rhinotracheitis Vaccine, Modified	1101.20	Grand	12/18/01
Live Virus		Laboratories, Inc.,	
		Est. 303	
Bovine Rhinotracheitis Vaccine, Modified	1101.22	Pfizer Inc.,	12/20/01
Live Virus		Est. 189	
Bovine Rhinotracheitis-Parainfluenza <sub>3</sub>	1121.20	Grand	11/06/01
Vaccine, Modified Live Virus		Laboratories, Inc.,	
		Est. 303	
Bovine Rhinotracheitis-Virus Diarrhea	1157.22	Pfizer Inc.,	12/20/01
Vaccine, Modified Live and Killed Virus		Est. 189	
Bovine Rhinotracheitis-Virus Diarrhea-	1187.22	Pfizer Inc.,	12/20/01
Parainfluenza <sub>3</sub> -Respiratory Syncytial Virus		Est. 189	
Vaccine, Modified Live and Killed Virus			

	Product	Establishment/	
True Name	Code	Permittee	Date
Bovine Virus Diarrhea Vaccine, Killed	1205.22	Pfizer Inc.,	12/20/01
Virus		Est. 189	
Equine Influenza Vaccine, Killed Virus	1505.24	American Home	12/04/01
		Products Corp.,	
		Est. 112	
Equine Rhinopneumonitis-Influenza	1515.26	American Home	11/20/01
Vaccine, Killed Virus		Products Corp.,	
		Est. 112	
Newcastle Disease Vaccine, B <sub>1</sub> Type,	1721.10	Biomune Co.,	11/13/01
LaSota Strain, Live Virus		Est. 368	
Newcastle-Bronchitis Vaccine, B <sub>1</sub> Type,	1761.18	American Home	04/05/01
B <sub>1</sub> Strain, Mass. Type, Live Virus		Products Corp.,	
		Est. 112	
Newcastle-Bronchitis Vaccine, Mass. and	1785.12	Merial Select, Inc.,	11/30/01
Ark. Types, Killed Virus		Est. 279	
Bovine Coronavirus Vaccine, Killed Virus	19N5.20	Grand	12/18/01
		Laboratories, Inc.,	
		Est. 303	
Infectious Salmon Anemia Virus Vaccine,	1A45.20	Jerry Zinn,	10/05/01
Killed Virus		Permit 335	
Aeromonas Salmonicida-Vibrio	2138.02	Jerry Zinn,	10/05/01
Anguillarum-Ordalii-Salmonicida Bacterin		Permit 335	
Mycoplasma Hyopneumoniae Bacterin	2775.00	ImmTech	11/20/01
		Biologics, LLC,	
		Est. 480	
Mycoplasma Hyopneumoniae Bacterin	2775.02	Intervet Inc.,	12/18/01
		Est. 286	
Bovine Rhinotracheitis Vaccine, Modified	4019.20	Grand	12/18/01
Live Virus, Leptospira		Laboratories, Inc.,	
Canicola-Grippotyphosa-Hardjo-		Est. 303	
Icterohaemorrhagiae-Pomona Bacterin			
Parvovirus Vaccine, Killed Virus,	4975.22	Grand	11/06/01
Leptospira Canicola-Grippotyphosa-		Laboratories, Inc.,	
Hardjo-Icterohaemorrhagiae-Pomona		Est. 303	
Bacterin			

	Product	Establishment/	
	Code	Permittee	Date
Infectious Salmon Anemia Virus Vaccine,	4A45.20	Jerry Zinn,	10/05/01
Killed Virus, Aeromonas		Est. 334	
Salmonicida-Vibrio Anguillarum-			
Ordalii-Salmonicida Bacterin			
Bovine Leukemia Virus Antibody Test	5505.20	ImmuCell Corp.,	11/30/01
Kit		Est. 327	
Mycobacterium Bovis Gamma Interferon	5A64.00	Biocor Animal	12/10/01
Test Kit for Cattle		Health Corp.,	
		Permit 462A	
Clostridium Perfringens Types C and D	8201.00	Grand	11/06/01
Toxoid		Laboratories, Inc.,	
		Est. 303	
Tetanus Toxoid	8601.03	American Home	12/05/01
		Products Corp.,	
		Est. 112	
Tetanus Toxoid	H601.02	American Home	12/05/01
		Products Corp.,	
		Est. 112E	

The following product licenses for Intervet Inc., Est. 286, were terminated without prejudice on October 18, 2001:

Bordetella Bronchiseptica-Mycoplasma Hyopneumoniae-Pasteurella Multocida Bacterin-Toxoid, Code 7085.01

Pasteurella Multocida, Killed Culture, Code H551.00

The following product licenses for Biocor Animal Health Inc., Est. 462, were terminated without prejudice on November 28, 2001:

Canine Distemper-Hepatitis Vaccine, Modified Live Virus, Code 1311.20

Pseudorabies Vaccine, Modified Live Virus, Code 1891.R1

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza<sub>3</sub> Vaccine, Killed Virus, Haemophilus Somnus Bacterin, Code 44H5.20

Canine Distemper-Hepatitis Vaccine, Modified Live Virus, Leptospira Bacterin, Code 4689.20

Center for Veterinary Biologics Notice No. 02-03

4

Pseudorabies Virus GPIII Antibody Test Kit, Code 5112.00

Leptospira Bratislava-Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Killed Culture, Code B680.00

Clostridium Perfringens Type C, Killed Culture, Code G800.00

The following product licenses for IDEXX Corporation, Est. 313, were terminated without prejudice on December 11, 2001:

Canine Borrelia Burgdorferi Antibody Test Kit, Code 5017.00

Bovine Leukemia Virus Antibody Test Kit, Code 5505.21

Mycoplasma Gallisepticum DNA Test Kit, Accessory F Strain, Code 5A75.00

Due to the acquisition of Maine Biological Laboratories, Inc., Est. No. 240, by Lohmann Animal Health International (formerly Immunogenetics, Inc.), Est. No. 196, the following products previously issued to Est. No. 240 have been reissued to Est. No. 196:

Autogenous Vaccine, Killed Virus, Code 1015.10

Avian Encephalomyelitis Vaccine, Killed Virus, Code 1055.10

Avian Influenza Vaccine, H10 Subtype, Killed Virus, Code 1057.H0

Avian Influenza Vaccine, H1 Subtype, Killed Virus, Code 1057.H1

Avian Influenza Vaccine, H2 Subtype, Killed Virus, Code 1057.H2

Avian Influenza Vaccine, H3 Subtype, Killed Virus, Code 1057.H3

Avian Influenza Vaccine, H4 Subtype, Killed Virus, Code 1057.H4

Avian Influenza Vaccine, H5 Subtype, Killed Virus, Code 1057.H5

Avian Influenza Vaccine, H6 Subtype, Killed Virus, Code 1057.H6

Avian Influenza Vaccine, H9 Subtype, Killed Virus, Code 1057.H9

Avian Paramyxovirus Vaccine, Type 3, Killed Virus, Code 10C5.10

Avian Paramyxovirus Vaccine, Type 1, Killed Virus, Code 10C5.11 Center for Veterinary Biologics Notice No. 02-03

Bronchitis Vaccine, Mass. and Conn. Types, Live Virus, Code 1231.14

Bronchitis Vaccine, Conn. Type, Live Virus, Code 1231.15

Bronchitis Vaccine, Mass. Type, Live Virus, Code 1231.16

Bronchitis Vaccine, Ark. Type, Live Virus, Code 1231.20

Bronchitis Vaccine, Mass. Type, Killed Virus, Code 1235.10

Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Code 1235.15

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Killed Virus, Code 1245.40

Bursal Disease Vaccine, Killed Virus, Code 1275.01

Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code 12B5.4A

Bursal Disease-Reovirus Vaccine, Killed Virus, Code 12D5.02

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12D5.45

Bronchitis-Bursal Disease-Reovirus Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12E5.4A

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12J5.63

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard and Variant, Mass. Type, Killed Virus, Code 12M5.01

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12M5.41

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Standard and Variant, Mass. and Ark. Types, Killed Virus, Code 12M5.42

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12P5.41

Newcastle Disease Vaccine, Killed Virus, Code 1705.11 Center for Veterinary Biologics Notice No. 02-03

Newcastle Disease Vaccine, B<sub>1</sub> Type, B<sub>1</sub> Strain, Live Virus, Code 1711.11

Newcastle Disease Vaccine, B<sub>1</sub> Type, LaSota Strain, Live Virus, Code 1721.11

Newcastle Disease Vaccine, Roakin Type, Live Virus, Code 1731.10

Newcastle Disease-Avian Encephalomyelitis Vaccine, Killed Virus, Code 1745.10

Mycoplasma Gallisepticum Vaccine, Live Culture, Code 1751.00

Newcastle-Bronchitis Vaccine, B<sub>1</sub> Type, B<sub>1</sub> Strain, Mass. and Conn. Types, Live Virus, Code 1761.15

Newcastle-Bronchitis Vaccine,  $B_1$  Type,  $B_1$  Strain, Mass. and Conn. Types, Live Virus, Code 1761.1H

Newcastle-Bronchitis Vaccine, B<sub>1</sub> Type, B<sub>1</sub> Strain, Mass. Type, Live Virus, Code 1768.12

Newcastle-Bronchitis Vaccine, B<sub>1</sub> Type, LaSota Strain, Mass. Type, Live Virus, Code 1771.1A

Newcastle-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Code 1785.10

Newcastle-Bronchitis Vaccine, Mass. Type, Killed Virus, Code 1785.11

Newcastle-Bronchitis Vaccine, B<sub>1</sub> Type, B<sub>1</sub> Strain, Mass. and Ark. Types, Live Virus, Code 17A3.1M

Newcastle-Paramyxovirus Vaccine, Type 3, Killed Virus, Code 17P5.10

Salmonella Typhimurium Vaccine, Live Culture, Code 19C1.01

Pasteurella Multocida Bacterin, Avian Isolates, Types 1 and 3X4, Code 2704.00

Salmonella Enteritidis Bacterin, Code 2785.00

Autogenous Vaccine, Killed Virus, Autogenous Bacterin, Code 4500.00

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, and 4, Code 4635.40 Center for Veterinary Biologics Notice No. 02-03

Newcastle Disease-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Salmonella Enteritidis Bacterin, Code 48D7.10

Newcastle Disease-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Salmonella Enteritidis Bacterin, Code 48D7.11

Avian Reovirus, Killed Virus, Code A045.02

Avian Encephalomyelitis Virus, Live Virus, Code A051.10

Avian Paramyxovirus, Type 3, Live Virus, Code A0C5.10

Bronchitis Virus, Mass. Type, Live Virus, Code A231.12

Bronchitis Virus, Mass. and Ark. Types, Killed Virus, Code A235.15

Bronchitis Virus, Mass. Type, Killed Virus, Code A235.16

Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus, Code A235.17

Bursal Disease Virus, Killed Virus, Code A275.10

Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code A2B5.40

Newcastle Disease Virus, B<sub>1</sub> Type, LaSota Strain, Killed Virus, Code A705.11

Newcastle Disease Virus, B<sub>1</sub> Type, B<sub>1</sub> Strain, Live Virus, Code A711.11

Newcastle Disease Virus, B<sub>1</sub> Type, LaSota Strain, Live Virus, Code A721.10

Newcastle-Bronchitis Vaccine, Mass. and Ark. Types, Killed Virus,

Code A785.10

Swine Influenza Virus, H1N1, Live Virus, Code A9A6.10

Pasteurella Multocida, Killed Culture, Avian Isolates, Types 1, 3, and 4, Code B702.13

Salmonella Enteritidis, Killed Culture, Code B785.00

Salmonella Enteritidis Bacterin, Code B785.01

Avian Influenza Virus, H7 Subtype, Live Virus, Code E004.00 Center for Veterinary Biologics Notice No. 02-03

Avian Reovirus, Live Virus, Code E041.00

Mycoplasma Meleagridis, Live Culture, Code E172.00

Bronchitis Virus, Mass. Type, Live Virus, Code E231.11

Bronchitis Virus, Killed Virus, Code E235.11

Bursal Disease Virus, Live Virus, Code E271.10

Bursal Disease Virus, Killed Virus, Code E275.10

Newcastle Disease Virus, B<sub>1</sub> Type, B<sub>1</sub> Strain, Live Virus, Code E711.10

Newcastle Disease Virus, B<sub>1</sub> Type, LaSota Strain, Live Virus, Code E721.10

Newcastle Disease Virus, B<sub>1</sub> Type, LaSota Strain, Killed Virus, E725.10

The following Est. No. 240 licenses are reissued to Est. 196 with different code numbers to avoid duplication of numbers:

Avian Reovirus Vaccine, Killed Virus, Code 1045.02 (formerly 1045.00)

Bronchitis Vaccine, Mass. Type, Live Virus, Code 1231.1F (formerly 1231.12)

Bronchitis Vaccine, Mass. and Ark. Types, Live Virus, Code 1231.1G (formerly 1231.13)

Bursal Disease Vaccine, Killed Virus, Code 1275.02 (formerly 1275.00)

Bursal Disease Vaccine, Standard and Variant, Killed Virus, Code 12B5.01 (formerly 12B5.40)

Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12D5.03 (formerly 12D5.00)

Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12D5.04 (formerly 12D5.01)

Bursal Disease-Newcastle Disease Vaccine, Standard and Variant, Killed Virus, Code 12G5.42 (formerly 12G5.41)

Center for Veterinary Biologics Notice No. 02-03

Bursal Disease-Newcastle Disease Vaccine, Killed Virus, Code 12G5.43 (formerly 12G5.40)

Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Mass. Type, Killed Virus, Code 12J5.41 (formerly 12J5.40)

Bursal Disease-Newcastle Disease-Bronchitis-Reovirus Vaccine, Mass. Type, Killed Virus, Code 12M5.91 (formerly 12M5.90)

Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant, Killed Virus, Code 12P5.43 (formerly 12P5.40)

Fowl Pox Vaccine, Live Virus, Code 1621.01 (formerly 1621.00)

Newcastle Disease Vaccine, Killed Virus, Code 1705.15 (formerly 1705.12)

Newcastle Disease Vaccine, B<sub>1</sub> Type, B<sub>1</sub> Strain, Live Virus, Code 1711.12 (formerly 1711.10)

Newcastle Disease Vaccine, B<sub>1</sub> Type, LaSota Strain, Live Virus, Code 1721.13 (formerly 1721.10)

Newcastle-Bronchitis Vaccine,  $B_1$  Type,  $B_1$  Strain, Mass. Type, Live Virus, Code 1761.A1 (formerly 1761.12)

Newcastle-Bronchitis Vaccine, B<sub>1</sub> Type, LaSota Strain, Mass. Type, Live Virus, Code 1771.12 (formerly 1771.11)

Pigeon Pox Vaccine, Live Virus, Code 1881.12 (formerly 1881.10)

Autogenous Bacterin, Code 2051.04 (formerly 2051.00)

Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, and 4, Code 2702.15 (formerly 2702.13)

Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, 4, and 3X4, Code 2703.18 (formerly 2703.15)

/s/Richard E. Hill, Jr.

Richard E. Hill, Jr. Director Center for Veterinary Biologics